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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,344	09/10/2004	Lauretta Maggi	28069-602 NATL	3801

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
06/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,344	MAGGI ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants': (1) response and (2) declaration, both filed on 10 March 2008.

* * * * *

Response to Amendment

The declaration under 37 CFR 1.132 filed on 10 March 2008 is insufficient to overcome the rejection of claims 1, 2, 3, 5, and 8-25 based upon the 35 USC 12(b) rejection in view of Conte as set forth in the last Office action because: the data disclosed in Exhibit A and Exhibit B do not control for formulation excipients such as binders, fillers, disintegrants, etc. Thus, it is not possible to conclude that the release profiles disclosed in the graphs of Exhibit A and Exhibit B are a sole function of coating structure. Furthermore, it is not clear what the difference is in the formulations EG 1-EG 8 of Exhibit A and Examples 1-6B of Exhibit B. Also not disclosed are the size, shape, and number of incisions in the tablets of Exhibit B. Without more information, examiner respectfully submits that it is not possible to determine the cause of any difference of release profiles between Exhibit A and Exhibit B.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 2, 4, 5, and 8-25 are rejected under 35 USC 102(b) as being anticipated by Conte US 5487901.

Conte discloses a pharmaceutical tablet composed of an upper layer containing active ingredient, formulated for immediate release, an intermediate layer that does not contain any active agents and is formulated with polymers as a semipermeable membrane, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being almost completely coated with an insoluble polymeric coating (col. 2, lines 30-45). The tablet is completely coated with an impermeable polymeric film (col. 2, lines 52-53). The upper layer also comprises polymeric excipients (col. 4, lines 1-9). The amount of the excipient with respect to the total weight of the tablet is 1-90% by wt (col. 4, lines 10-13). The upper layer is 0.5-5 mm thick (col. 4, line 39). The intermediate layer is made of gelable or erodible polymers (col. 4, lines 40-53). The amount of polymeric substance in respect of the total weight of the tablet is 5-90% (col. 4, lines 55). The intermediate layer is 0.1-4.5 mm thick (col. 5, lines 31). The third layer has the same composition as the upper layer (col. 5, lines 32-36). The lower layer is 0.5-5 mm thick (col. 5, line 37). The tablet is coated with an impermeable polymeric material that is insoluble or exhibits delayed solubility, or a solubility that is pH dependent (col. 5, lines 40-46). The polymeric coating in respect of the finished tablet is 0.2-20% by wt (col. 5, lines 54-55). The upper layer is partially

exposed to the environmental fluid because a raised portion was removed after final coating with impermeable polymeric coating (col. 2, lines 54-55). The reference discloses that the removal of the raised portion may be carried out by techniques already available on the market (col. 5, lines 61-64). This teaching does not rule out using laser to remove the raised portion. In any case, as was stated above in the previous rejection, claim 1 is a product by process claim. The process by which a product is made will only hold patentable weight if the process imparts functional or structural limitations to the product that would distinguish it from the product of the prior art. In this case the prior art clearly anticipates the instant claimed product, and therefore the process limitation of using a laser to incise the impermeable polymeric membrane in the product claims does not impart patentable weight. The burden is upon applicant to show that instant product is patentably distinct from Ayer's product.

*

2. Claims 1,2, 4, 5, 8-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte et al. US 5650169.

Conte '169 is a divisional of Conte '901. The disclosures are identical and the disclosure of '169 discloses all of the limitations discussed in the previous rejection. See above.

*

3. Claims 1, 3, 6-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Faour US 6599284 B2.

Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredient (2), an intermediate layer forming a semipermeable membrane (3), and an inner layer or core containing active ingredient (4) (Figure 4). The dosage form also comprises a passageway (5) formed by laser incision (col. 13, lines 48-55), which is incised in correspondence with both the first and third layer (Figure 4). The reference also teaches the addition of osmopolymers (col. 16, lines 1--45), and disintegrating agents (col. 18, lines 25-38)° The reference further discloses that the outer layer or external coating layer may contain the same or different active ingredients as the inner layer (col. 13, lines 5-7). Example 1 discloses the composition of the inner core, which comprises more then 49% by wt polymeric material (col. 24, lines 15-25). Example 1 also discloses the use 5% by wt of polyethylene glycol (col. 24, lines 25-30). Faour incorporated by reference Theeuwes et al. US 4088864, which discloses the laser source as C02 and the output of 20W. Therefore the process claims are also anticipated by this reference.

* * * * *

Response to Arguments

Applicants' arguments filed on 10 March 2008 have been fully considered but they are not persuasive.

1. Applicants argue, "[t]he Examiner asserts that the method by which the tablet of claims 1, 2, 4, 5, and 8-25 is made is different from the method described in Conte but that the process by which the claimed product is made will only hold patentable weight if the process imparts function or structural limitations to the product that would

distinguish it from the product of Conte, and that the process limitation of using a laser to incise the impermeable polymeric membrane in the product claims does not impart patentable weight." *See* remarks, page 5.

In order to clarify examiner's position regarding product-by-process claims, the following is a quotation from MPEP 2113:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).
>
> >The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)<

Based on the instant claim language, examiner respectfully submits that the structure of the instant tablet is anticipated by the prior art, as explained below.

2. Applicants argue that the instantly claimed tablet is structurally different from the Conte tablet due to the laser incisions. *See* remarks, paragraph bridging pages 5 and 6.

Examiner respectfully submits that the broad claim language of instant claim 1 renders the instantly claimed tablet structurally and functionally equivalent to the tablets of the prior art. Claim 1 recites (in-part): "...said film coating...containing one or more laser-generated incisions delimiting an area of geometric shape and predetermined dimensions as a function of desired release times..." (emphasis supplied). Thus, the claim has no upper limit for incisions. As currently claimed, the instant tablet may have billions (or more) of incisions, so long as the incisions delimit an area of geometric shape. If the geometric shape is in the form of a circle or ring (which the instant claim language allows) then the instant tablet will be structurally and functionally equivalent to Conte's tablet.

3. Applicants argue that the release profile of the instantly claimed tablet is more advantageous than that of Conte. *See* remarks, page 6, first full-paragraph.

Please see "Response to Amendment," above.

4. Applicants argue that Faour discloses a preformed passageway generated by a laser while applicants are claiming a film with one or more laser incisions. *See* remarks, page 7.

As explained in response 2, above, the instant claims do not set an upper limit of the number of incisions that the instantly claimed tablet may have. Thus, examiner respectfully submits that the instantly claimed tablet with billions of incisions in the

shape of a passageway will be structurally and functionally equivalent to that disclosed by Faour.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618